AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 39

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00003	See Block 16C	OS262588	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES	ASPR-BARDA02
200 Independence Ave., S.W.		ASST SEC OF PREPAREDNESS & RESPONSE	
Room 640-G		ACQ MANAGEMENT, CONTRACTS, & GRANTS	
Washington DC 20201		O'NEILL HOUSE OFFICE BUILDING	
		Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

MODERNATX, INC 1492235
Attn: [redacted]
MODERNATX, INC. 200 TECHNOLOGY
200 TECHNOLOGY SQ
CAMBRIDGE MA 021393578

CODE 1492235 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034

10B. DATED *(SEE ITEM 13)* 04/03/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $471,596,459.00
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 27-0226313
DUNS Number: 069723520
The purpose of this modification is to support the additional scope of the Clinical Development Plan including direct increases to the clinical subcontractors on the P201 (Work Breakdown Structure 1.4.2.1) and P301 (Work Breakdown Structure 1.4.3.1) clinical studies, and forecasted overruns across the remaining WBS elements. This modification with Moderna to develop a mRNA vaccine for SARS-CoV-2 is part of the USG effort to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures) in the midst of a global novel coronavirus pandemic.

As a result of the additional scope, the following was updated in this modification.
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Stephane Bancel, Chief Executive Officer	WENDELL CONYERS

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
S. Bancel *(Signature of person authorized to sign)*	7-25-20	Wendell Conyers -S Digitally signed by Wendell Conyers -S Date: 2020.07.25 16:39:00 -04'00' *(Signature of Contracting Officer)*	07-25-2020

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	- Increase in total contract value from $483,298,520 to $954,894,979; - Section B.4.14 Enrollment Chart - Section C.2 Statement of Work - Section C.2.1 Development Approach - Section F.1.6. Organizational Chart - Section F.1.7. Contractor Provided Facilities, Infrastructure and Other Resources - Section F.2 Deliverables - Section F.3 Contract WBS Milestones/Deliverables and Technical Deliverables - Section H.3 Key Personnel - Section H.9 Security - Section H.20 Organizational Conflicts of Interest - Section H.21 Disclosure of Information - Section H.22 Publication and Publicity - Section H.23 Vetting Period of Performance: 04/03/2020 to 08/31/2023 Change Item 2 to read as follows(amount shown is the obligated amount):				
2	Base CLIN 0002 - Development of mRNA vaccine to BLA Accounting Info: (b) (4) Funded: $0.00 Accounting Info: (b) (4) Funded: $471,596,459.00				471,596,459.00

CONTINUATION PAGE

1. Modification Purpose

The purpose of this modification is to support the additional scope of the Clinical Development Plan including direct increases to the clinical subcontractors on the P201 (Work Breakdown Structure 1.4.2.1) and P301 (Work Breakdown Structure 1.4.3.1) clinical studies, and forecasted overruns across the remaining WBS elements. This modification with Moderna to develop a mRNA vaccine for SARS-CoV-2 is part of the USG effort to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures) in the midst of a global novel coronavirus pandemic.

As a result of the additional scope, the following was updated in this modification.

- Increase in total contract value from $483,298,520 to $954,894,979;
- Section B.4.14 Enrollment Chart
- Section C.2 Statement of Work
- Section C.2.1 Development Approach
- Section F.1.6. Organizational Chart
- Section F.1.7. Contractor Provided Facilities, Infrastructure and Other Resources
- Section F.2 Deliverables
- Section F.3 Contract WBS Milestones/Deliverables and Technical Deliverables
- Section H.3 Key Personnel
- Section H.9 Security
- Section H.20 Organizational Conflicts of Interest
- Section H.21 Disclosure of Information
- Section H.22 Publication and Publicity
- Section H.23 Vetting

2. Modification to Contract

This modification adds $471,596,459 to CLIN 0002 and increases the total contract value from $483,298,520 to $954,894,979. (b) (4)

(b) (4)

CLIN 0003 POP extends to (b) (4) at no additional cost.

Period	CLIN	Awarded 4/16/2020	Additional Scope	Total Contract
Pre Award	CLIN 0001	(b) (4)	(b) (4)	(b) (4)
Base	CLIN 0002	(b) (4)	$471,596,459	(b) (4)
Option 1	CLIN 0003	(b) (4)	$0	(b) (4)
Total		$483,298,520	$471,596,459	$954,894,979

The period of performance changes

From: (b) (6)

To: (b) (6) - August 31, 2023

B.4.14 Enrollment Chart

[redacted]

	Unit Price	Unit Qty	Total

[redacted]

C.2 Statement of Work (Revised 7-14-2020) Updates to WBS 1.4.2.1 and 1.4.3.1 Only

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA-1273 Vaccine Development (WBS 1.0)
The Contractor, ModernaTX, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (hereafter referred to as "mRNA-1273"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)
mRNA-1273 Program Management (WBS 1.1.1)
Moderna's mRNA-1273 program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs, Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA-1273. The Principal Investigator will set the strategic objectives for the program and ensure that Moderna is prepared to license a vaccine as early as the end of 2020. The Sub Principal Investigator will be responsible for ensure sufficient manufacturing capacity and production of mRNA-1273. . A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA-1273 project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be will delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)
Development and Reproductive Toxicology of mRNA-1273 (WBS 1.2.2.1)
To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Nonclinical (WBS 1.3)
For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)

(b) (4)

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA-1273.(b) (4)

(b) (4)

Establish a Surrogate of Protection (WBS 1.3.3.2)

The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1

clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.
Clinical (WBS 1.4)

(b) (4)

***Phase 2 Safety and Immunogenicity Study* (WBS 1.4.2.1) - Updated**

(b) (4)

Phase 3 Pivotal Study:(WBS 1.4.3.1) - Updated

Phase 3 Pivotal Study (WBS 1.4.3.1). The Phase 3 mRNA-1273-P301 study will confirm the trends observed during the Phase 1 and 2 trials, evaluating safety and efficacy in a larger number of subjects aged 18 and above. Approximately 30,000 subjects will be enrolled according to 1:1 randomization (active: placebo). Primary objectives will be 1) to demonstrate the efficacy of mRNA-1273 to prevent COVID-19

and 2) to evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart. (b) (4)

(b) (4)

Lot to Lot Consistency (WBS 1.4.3.2)

(b) (4)

Pediatrics (WBS 1.4.3.3)

(b) (4)

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA-1273 within the first 90 days of the contract. An original investigational new drug application (IND) will

be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

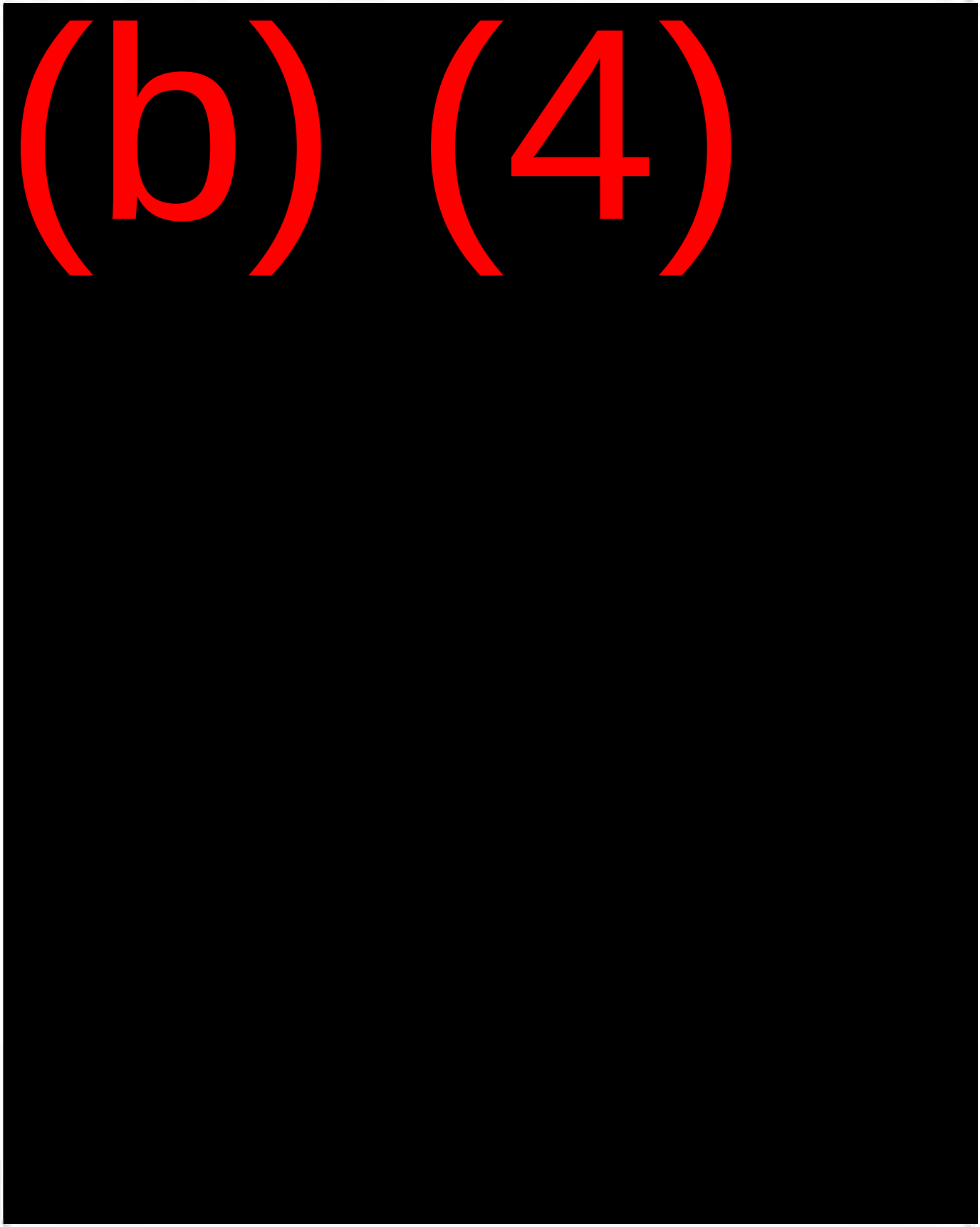
IND Maintenance (WBS 1.5.1.2)
The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)
Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA-1273 vaccine.
CMC (WBS 1.6)
CTM Manufacture for Phase 2 (WBS 1.6.3.2)
Clinical trial materials for the P201 study will be supplied using the AMP process. (b) (4)

(b) (4)

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)
mRNA Process Development
Technical Development will confirm and optimize the process parameters for mRNA manufacture. (b) (4)

(b) (4)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BLA Readiness (WBS 1.6.3.8)
In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)
The following section outlines the process development activities (b) (4) (b) (4) The goal of this work is to demonstrate the capability to produce mRNA-1273 at a scale that can support clinical demand.

(b) (4)

(b) (4)

Stability Studies (WBS 1.6.5.4)
Throughout the program, many studies will be undertaken (b) (4)
(b) (4) This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

C.2.1. Development Approach

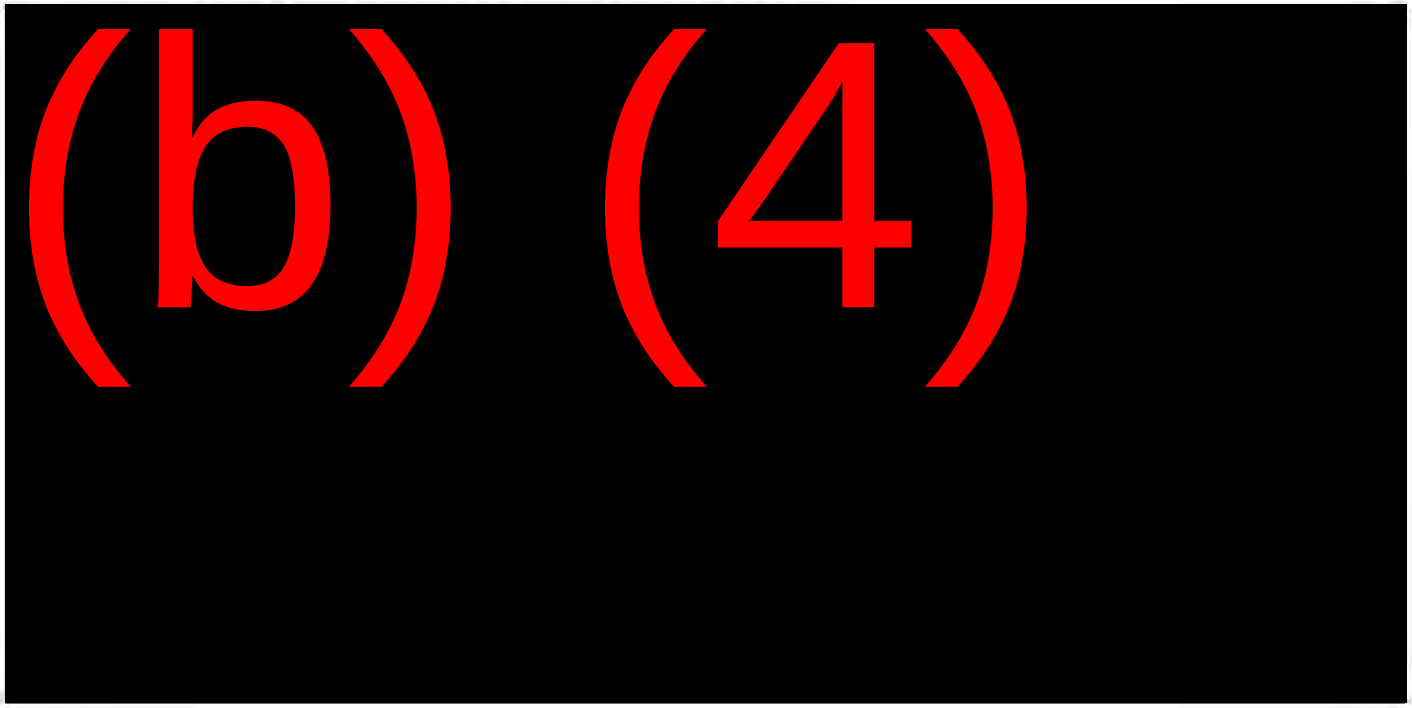
(b) (4)

5. (b) (4)

(b) (4)

Background for mRNA-1273 Program

(b) (4)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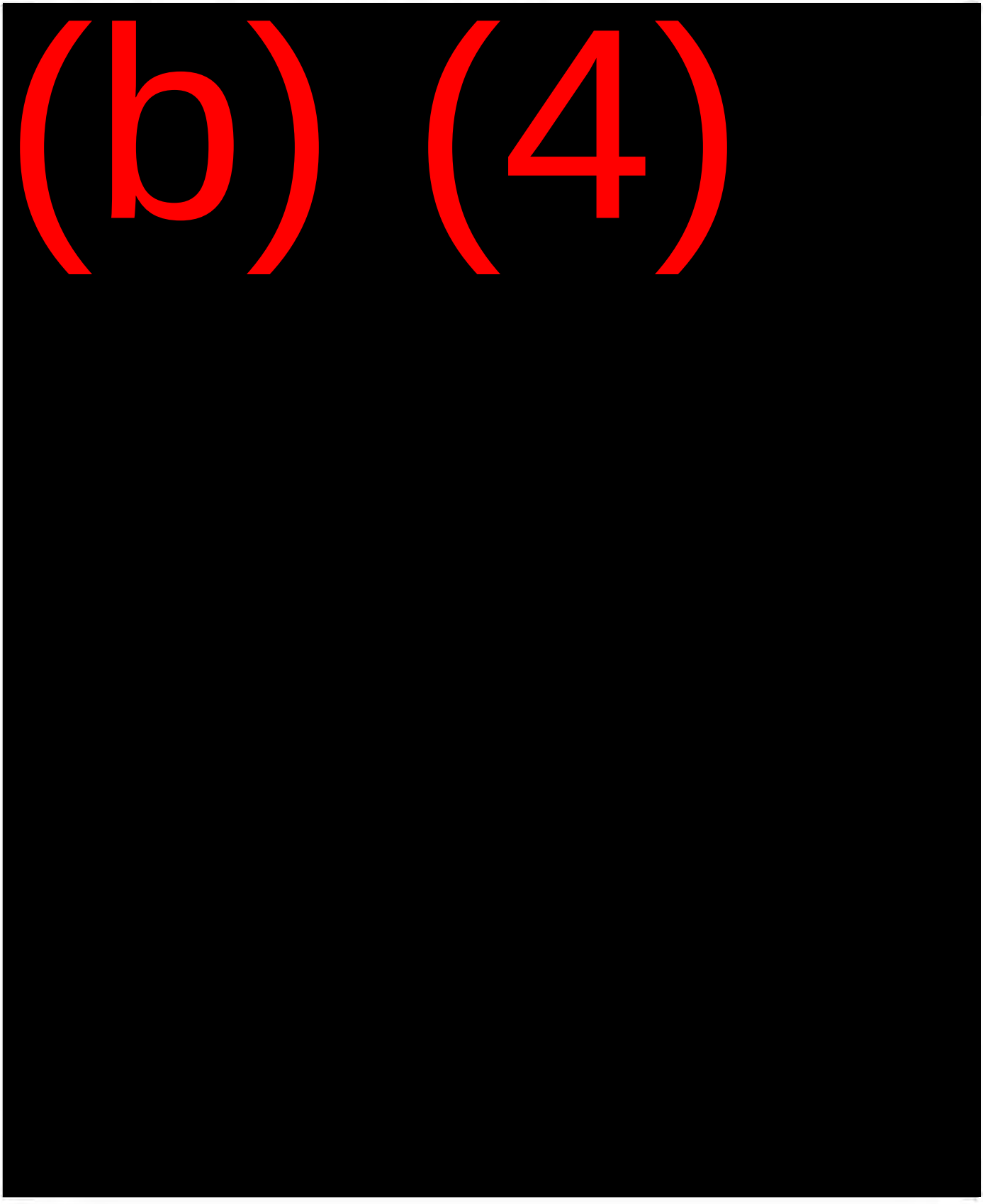
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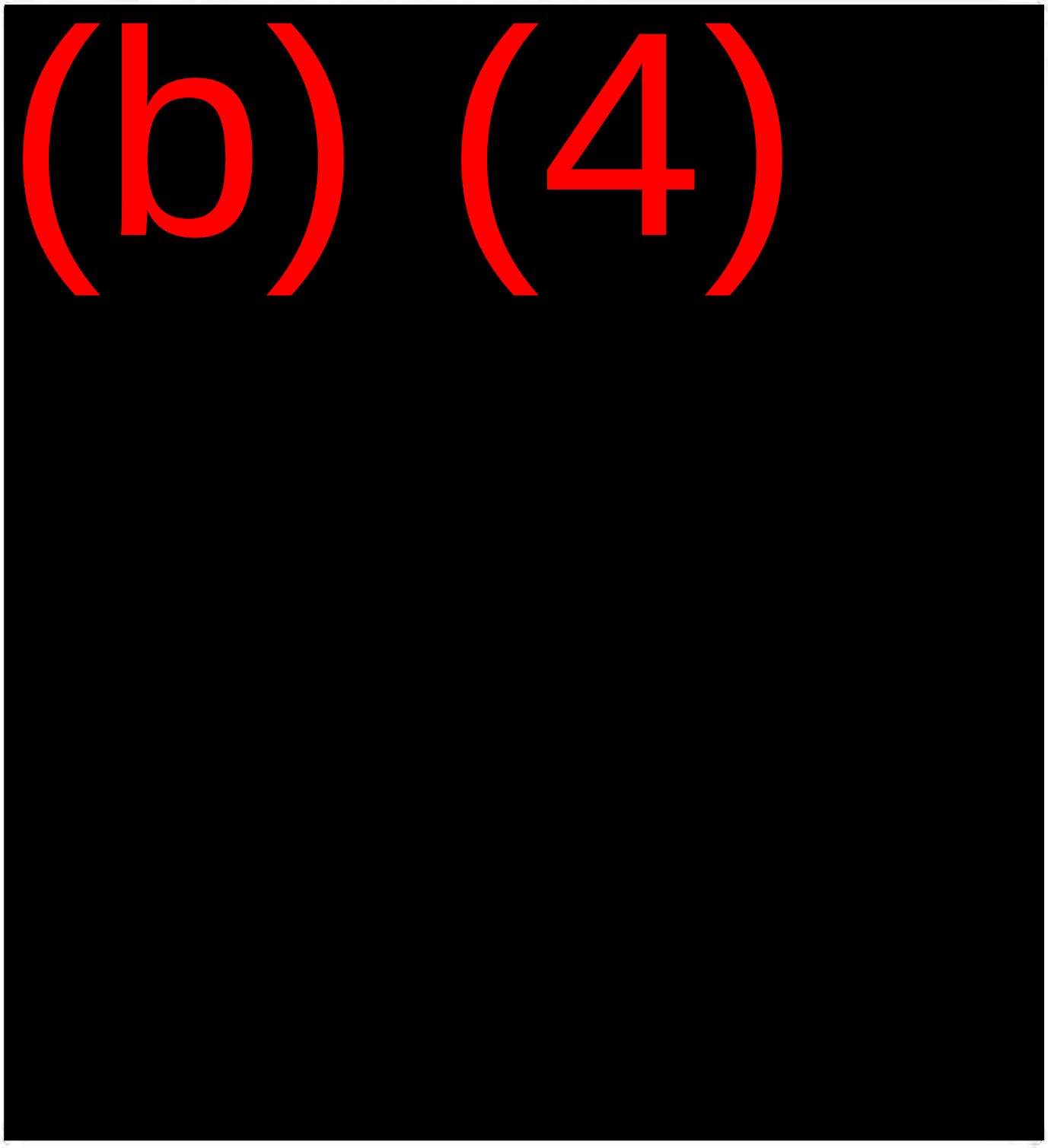
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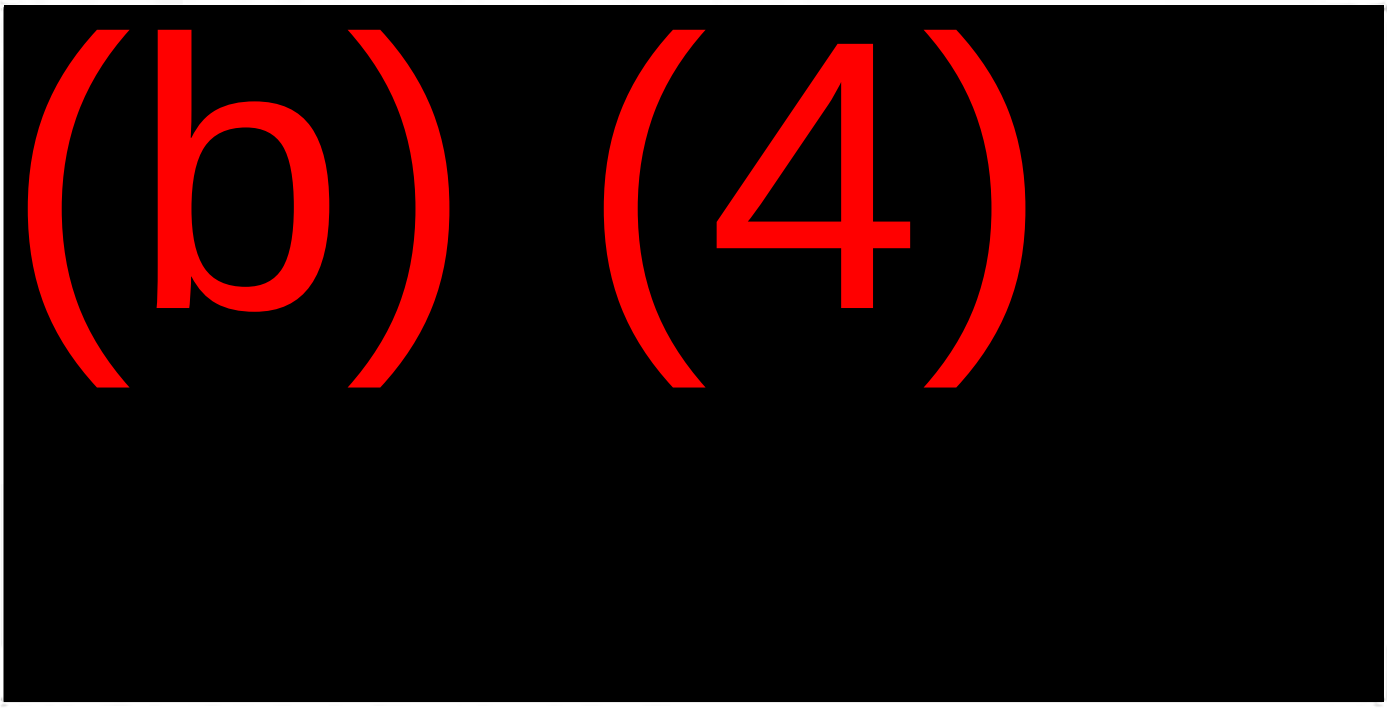
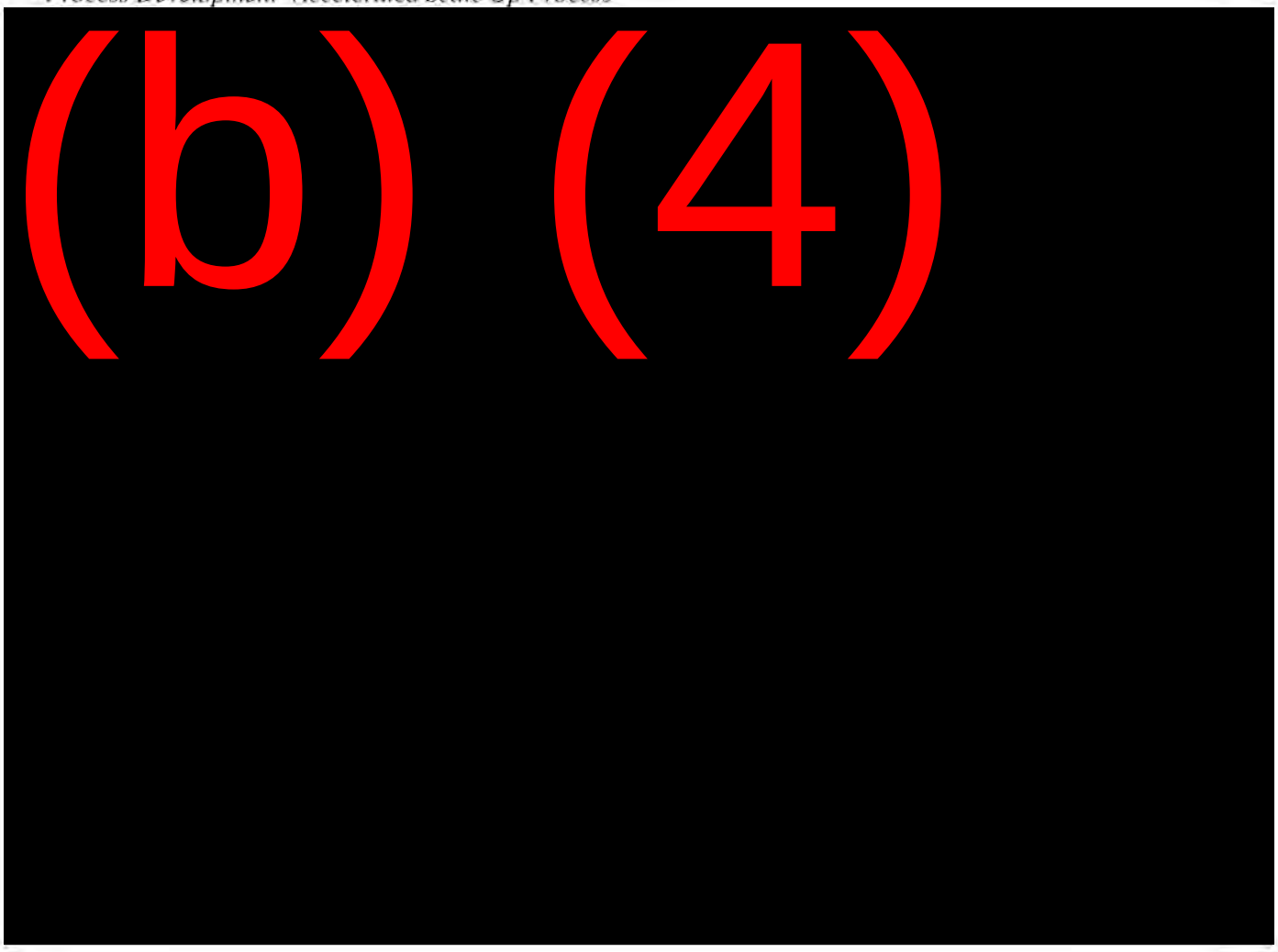
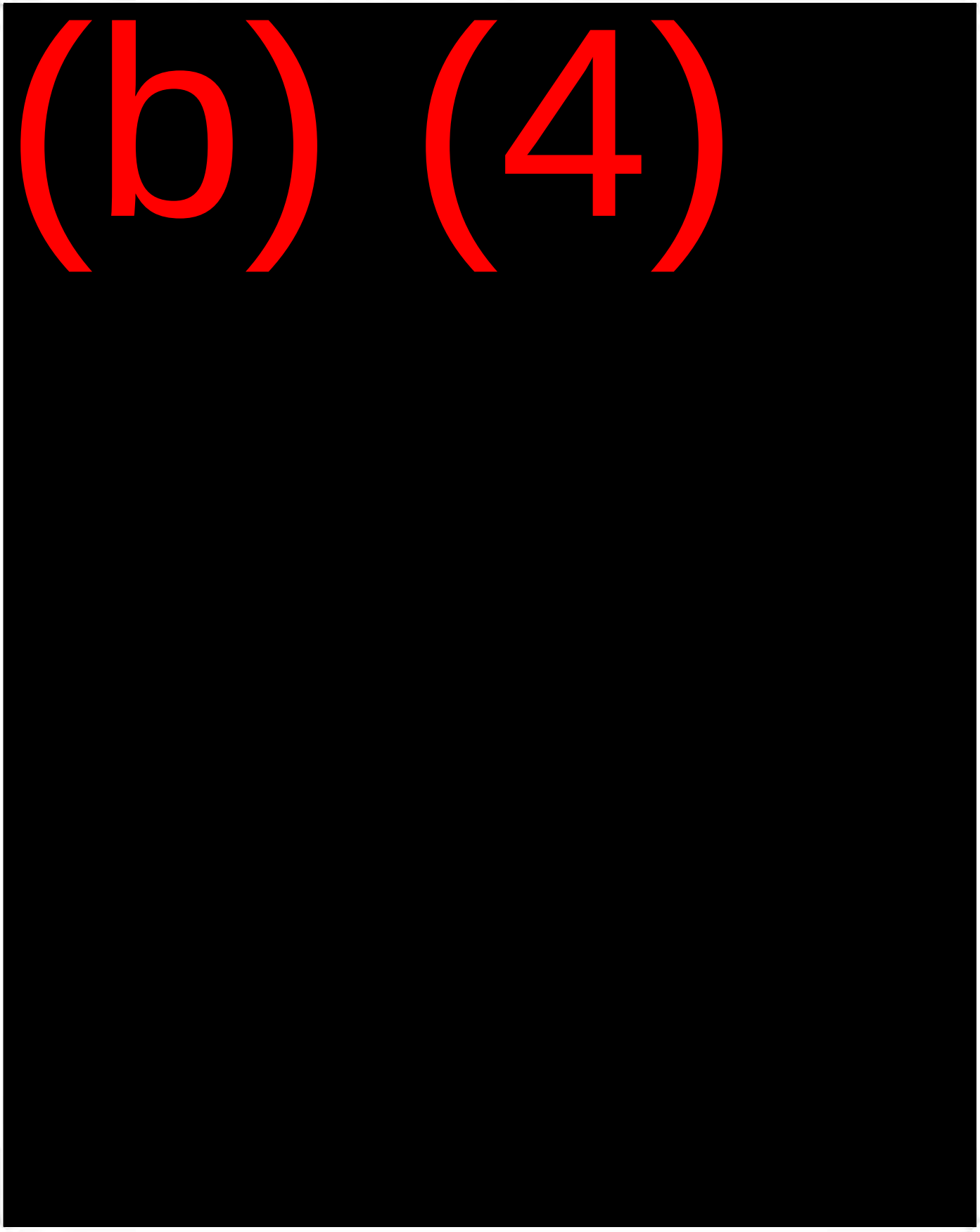


Process Development- Accelerated Scale Up Process

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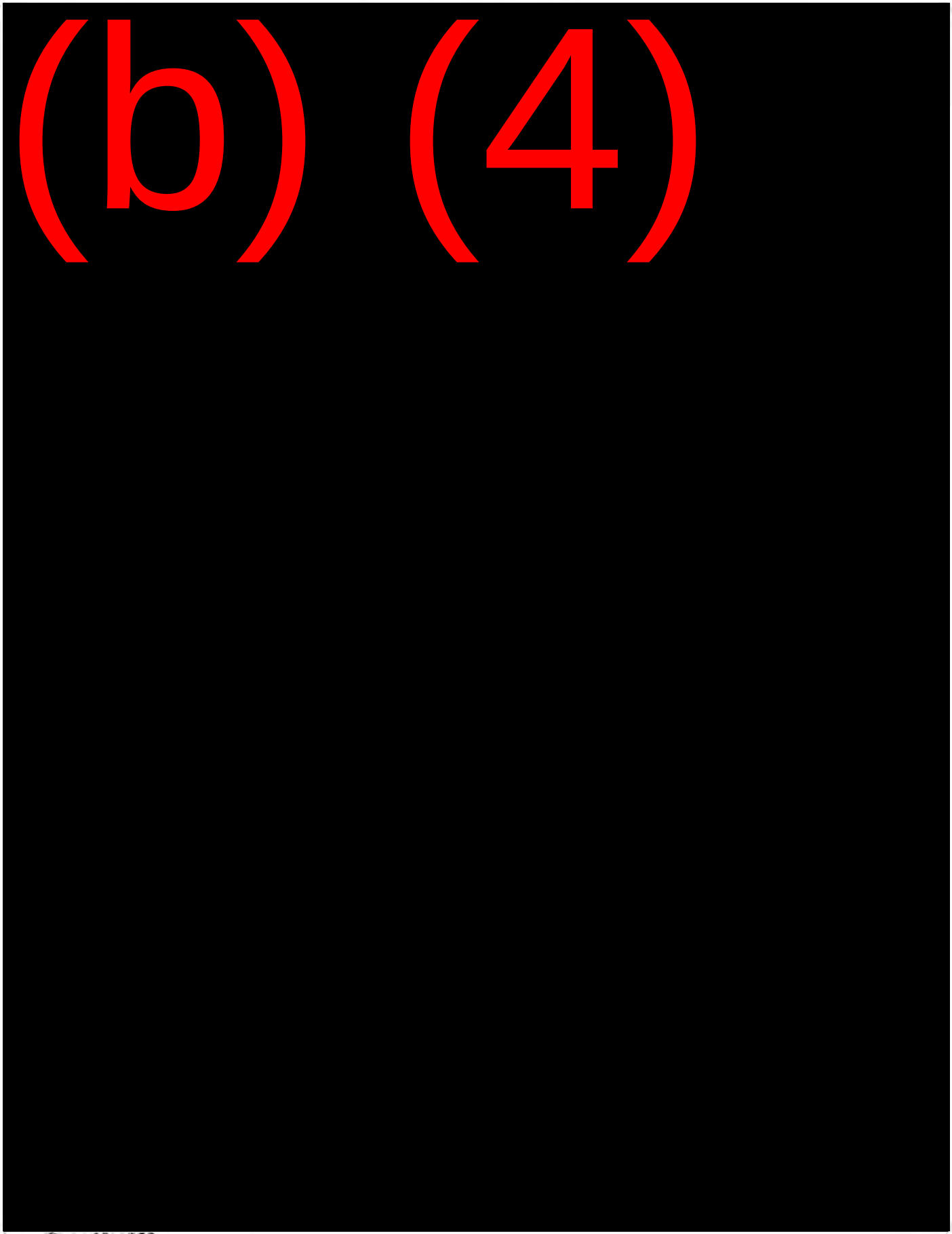
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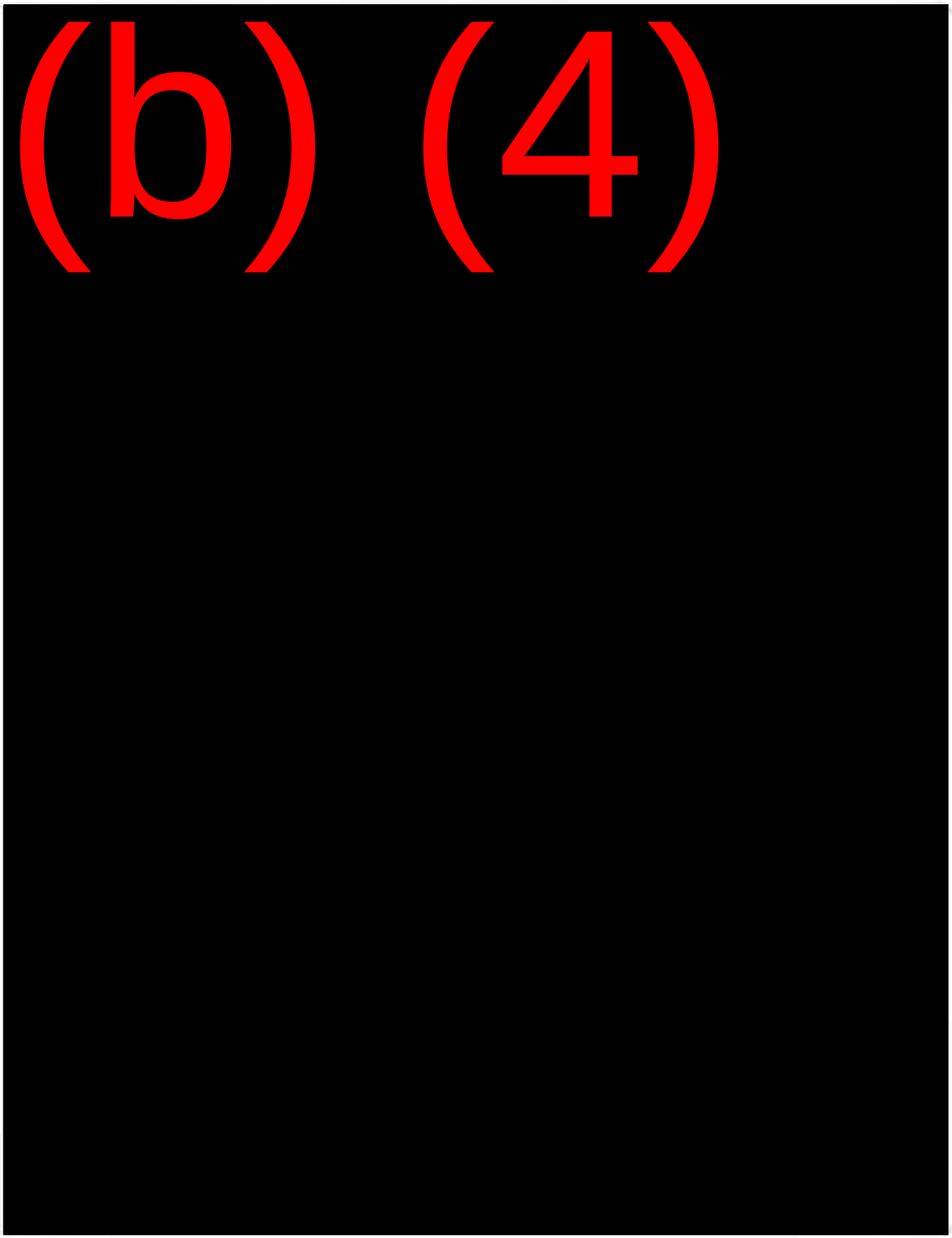
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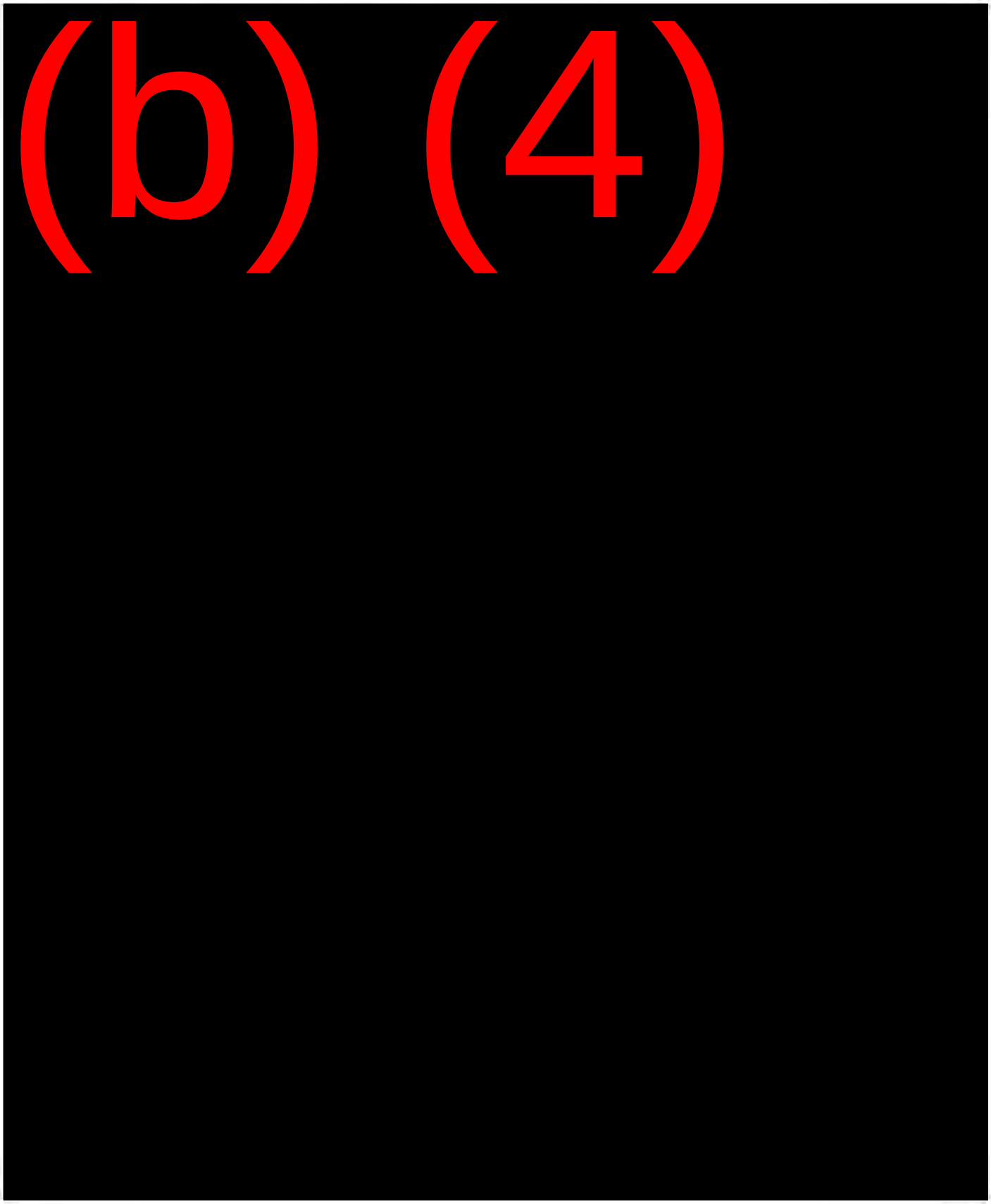
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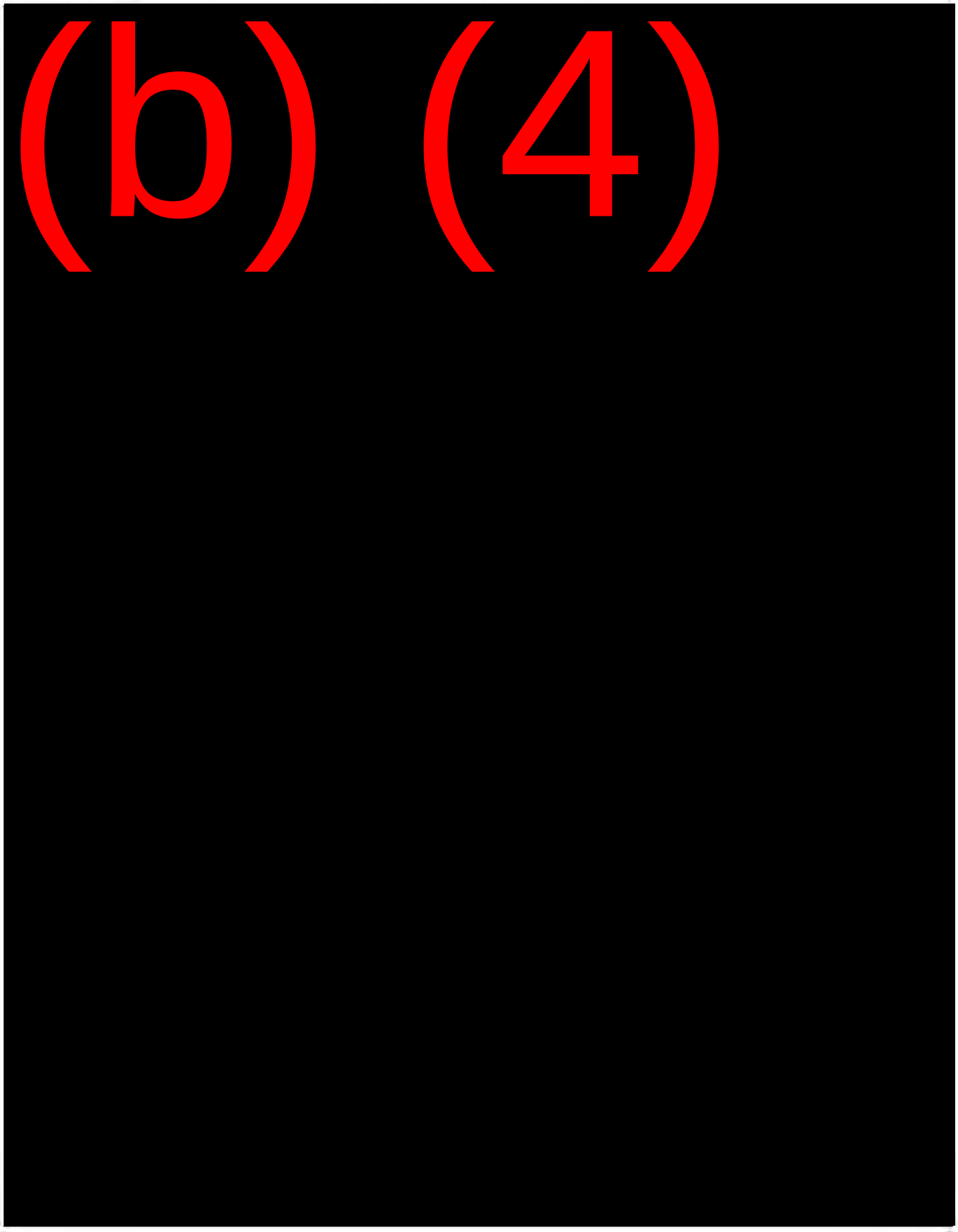
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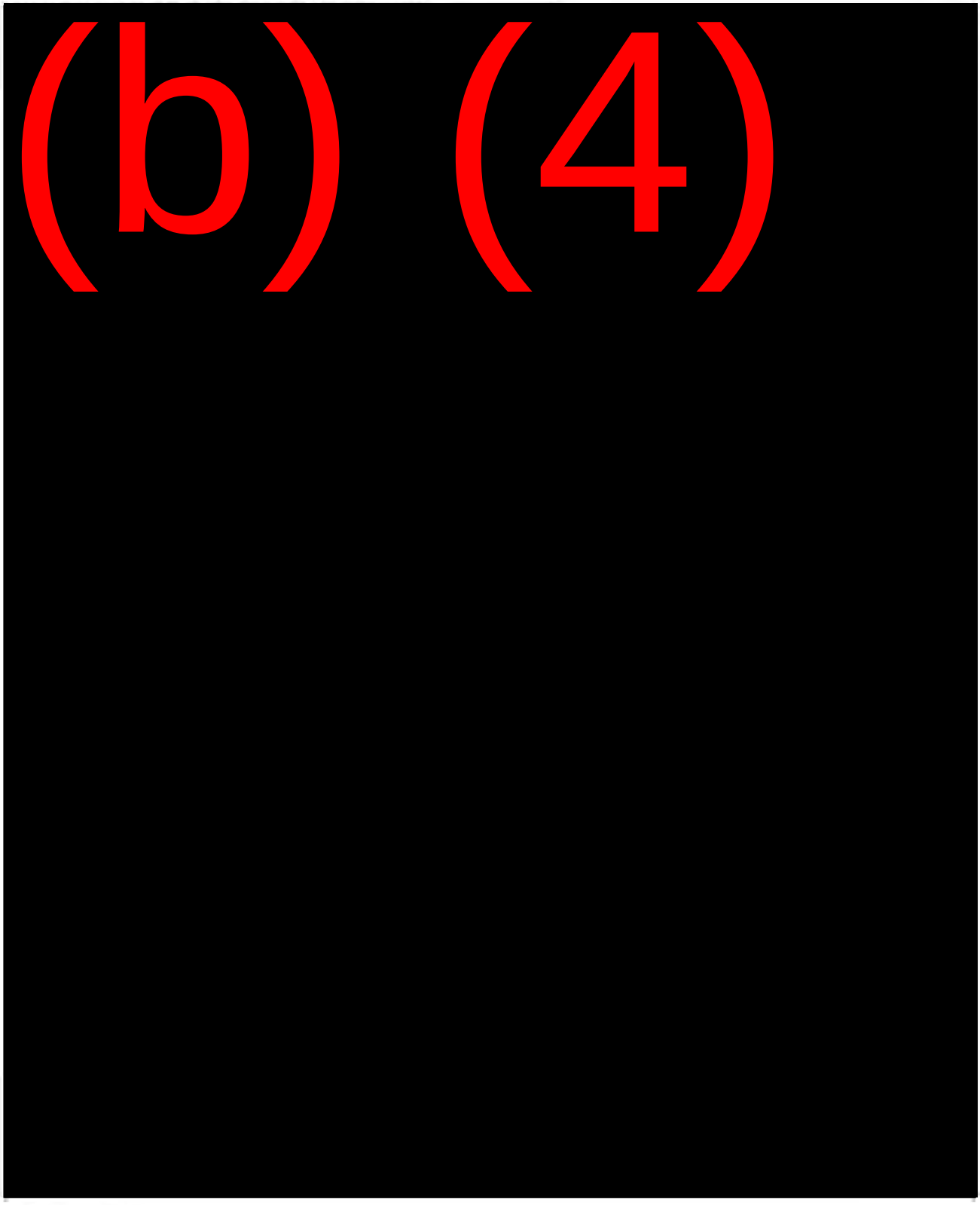
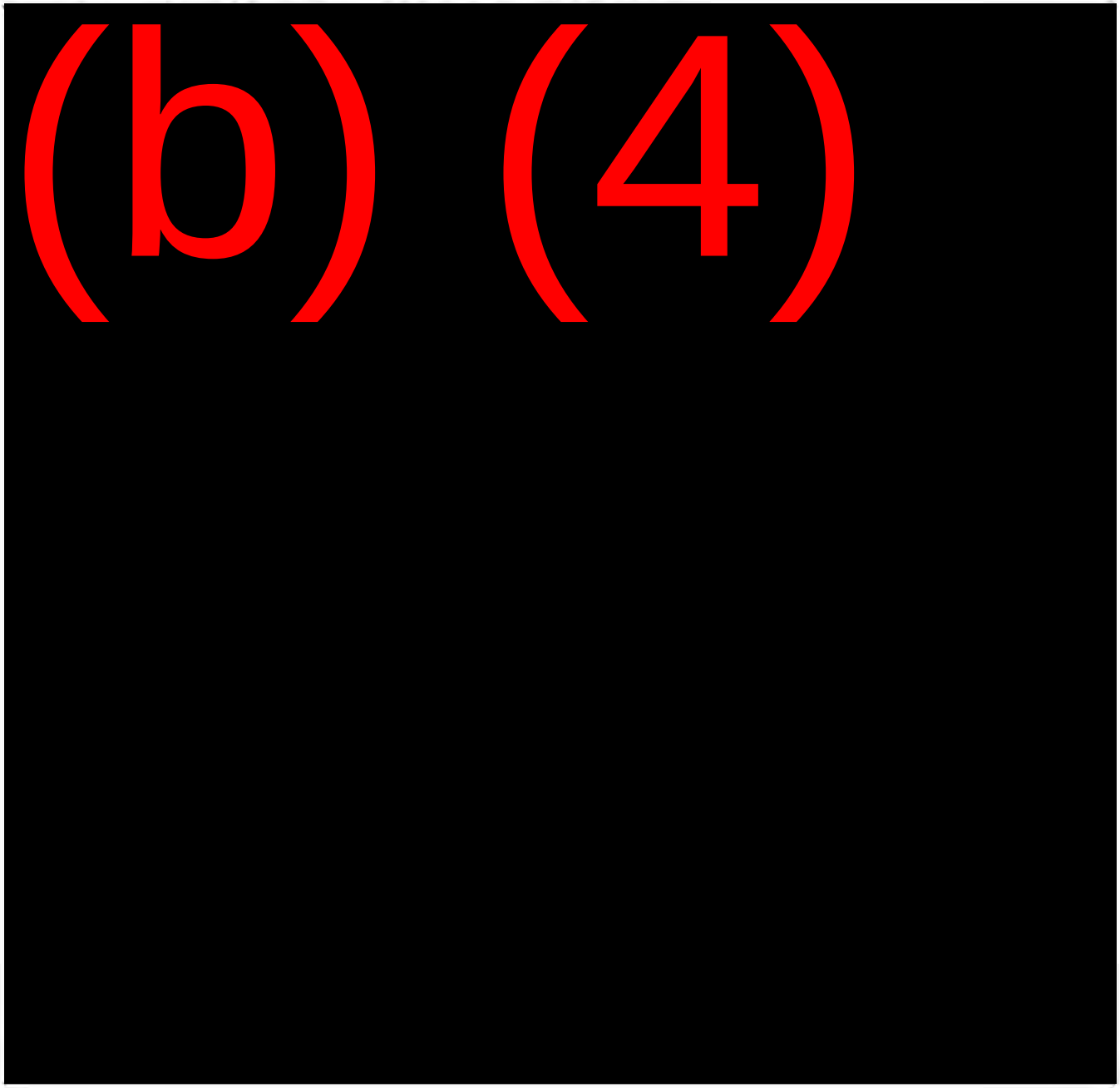
F.3 Contract WBS Milestones/Deliverables and Technical Deliverables

Work Breakdown Structure (WBS), Go/No Go Program Stage Gates Gantt Chart, Integrated Master Schedule (IMS)

Work Breakdown Structure and Option Periods

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F.3. Deliverables

The primary deliverable of this proposal is a licensed mRNA-1273 vaccine. In addition, the team, in partnership with BARDA, will also design a plan to enhance Moderna's ability to rapidly respond to a Coronavirus pandemic by leveraging our mRNA platform. Interim deliverables are presented below.

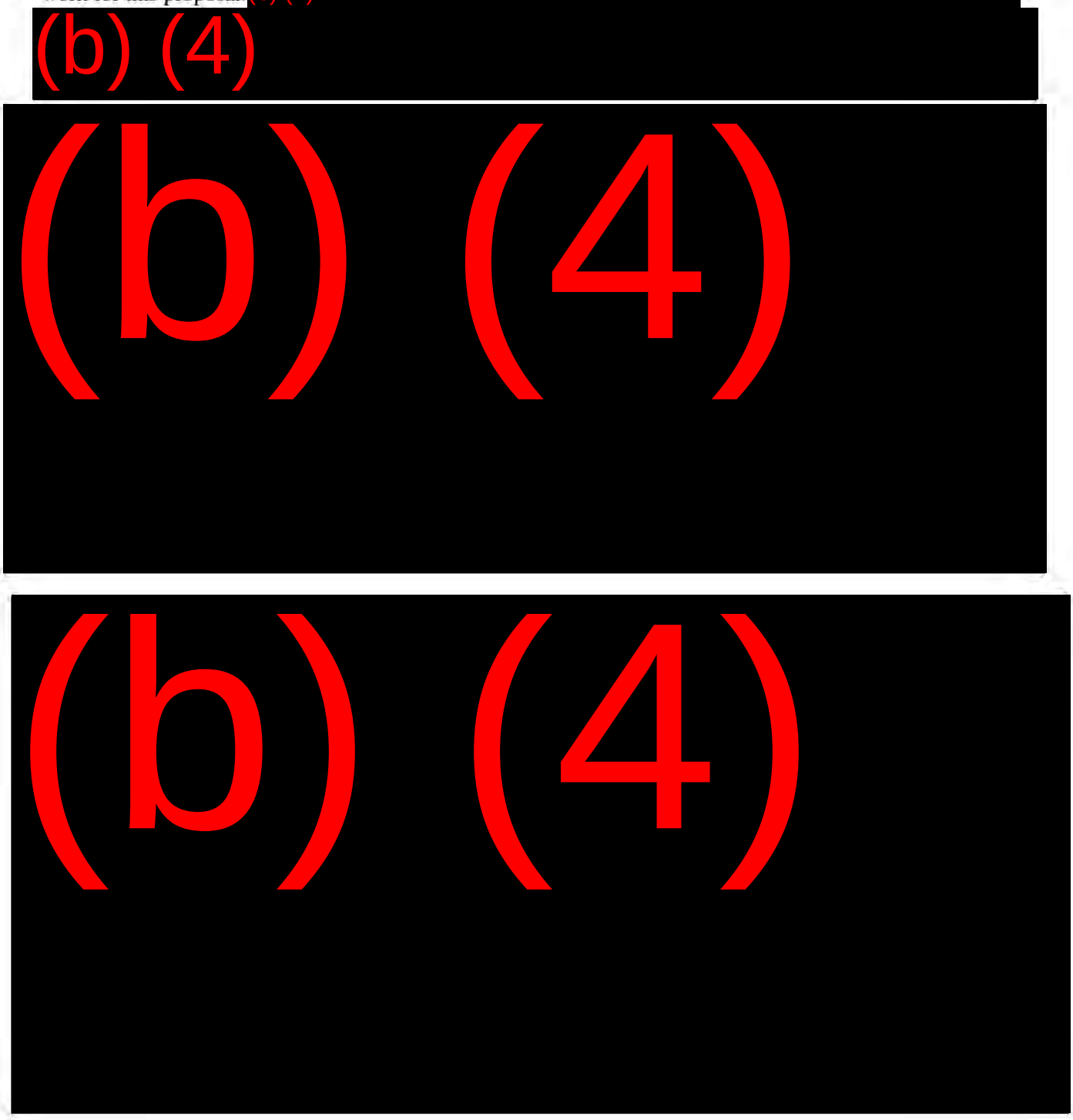
WBS	Title	Deliverable	Timing
1	mRNA-1273 Vaccine Development		
1.1	Program Management		
1.1.1	Program and Alliance Management	-Management Plans; Routine Reporting Deliverables	(b) (4)
1.2	Nonclinical Toxicology		
1.2.2	Safety		
1.2.2.1	Development and Reproductive Toxicology	- Final Study Report	
1.3	Nonclinical		
1.3.1	Model Development (reserved)		
1.3.1.2	NHP Efficacy Study	- Final Study Report	
1.3.1.3	Mouse Efficacy Study	- Final Study Report	
1.4	Clinical		
1.4.2	Phase 2		
1.4.2.1	Phase 2 Safety and Immunogenicity Study	- Clinical Study Protocol - Final Clinical Study Report	
1.4.3	Phase 3		
1.4.3.1	Phase 3 Efficacy or Safety and Immunogenicity	- Clinical Study Protocol - Final Clinical Study Report	
1.4.3.2	Phase 3 Lot-to-Lot	- Clinical Study Protocol - Final Clinical Study Report	
1.4.3.3	Phase 3 Adolescents	- Clinical Study Protocol - Final Clinical Study Report	
1.5	Regulatory		
1.5.1	IND		
1.5.1.1	IND Filing	- NA	
1.5.1.2	IND Maintenance	- Record of FDA Communications	
1.5.2	BLA		
1.5.2.1	BLA Submission	- NA	
1.6	CMC		
1.6.3	Pilot Scale Manufacturing		
1.6.3.2	CTM Manufacture for P201	- CoA for Clinical Lots	
1.6.3.4	CTM Manufacture for P301	- CoA for Clinical Lots	
1.6.3.6	CTM Manufacture for P302/P303	- CoA for Clinical Lots	

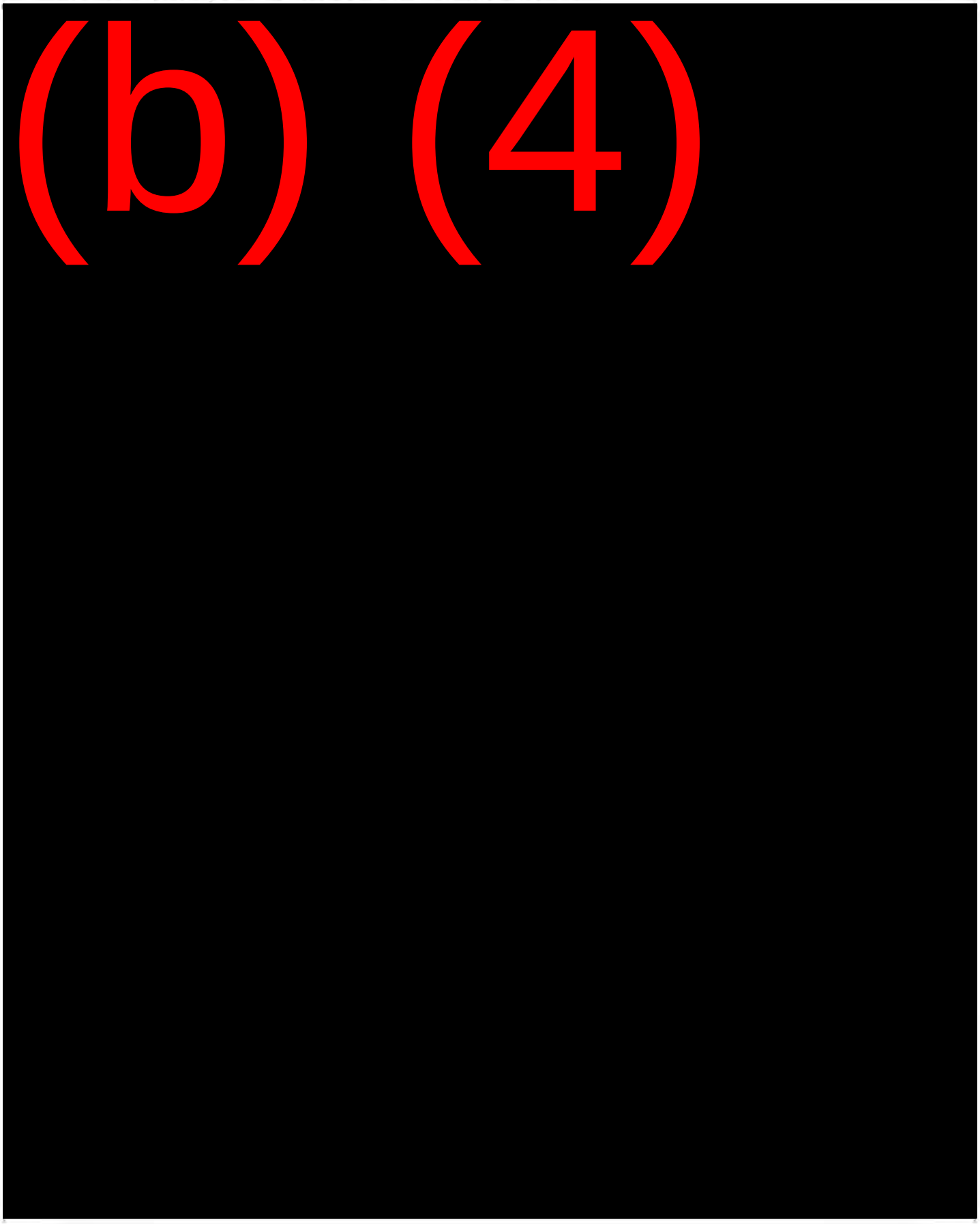
H.3 Key Personnel

mRNA-1273 Project Team	Name	Title
Principal Investigator	(b) (6)	CMO and Head of Clinical Development
Sub-Principal Investigator		Chief Technical Operations and Quality Officer
Program Lead (Point of Contact)		Director, Program Lead, Infectious Diseases
CMC PMO Lead		Head, COVID CMC PMO
Nonclinical Toxicology Lead		Director, Toxicology
Nonclinical Lead		Head, Infectious Diseases Research
Nonclinical		Assoc. Director, Infectious Diseases
Nonclinical		Assoc. Director, Infectious Diseases
Clinical Medical Director		Infectious Disease Development, Therapeutic Head
Clinical Medical Director Study Lead		Head, Public Health Vaccines
Clinical Medical Director		Director, Clinical Development
Clinical Operations Study Lead		Sr. Director, Clinical Operations, Infectious Diseases
Clinical Operations		Chief Development Officer
Clinical Biomarkers		Assoc. Director, Clinical Biomarkers
Regulatory Strategy		Head, Regulatory Strategy, Infectious Disease
CMC Technical Development Lead		SVP, Technical Development
CMC Technical Development		Director, Analytical Technical Ops
CMC Manufacturing		Head, Supply Chain
Quality Lead		SVP, Global Quality

F.1.6. Organizational Chart

The organizational chart depicts the project team reporting structure of the key personnel for the scope of work for this proposal.(b) (4)

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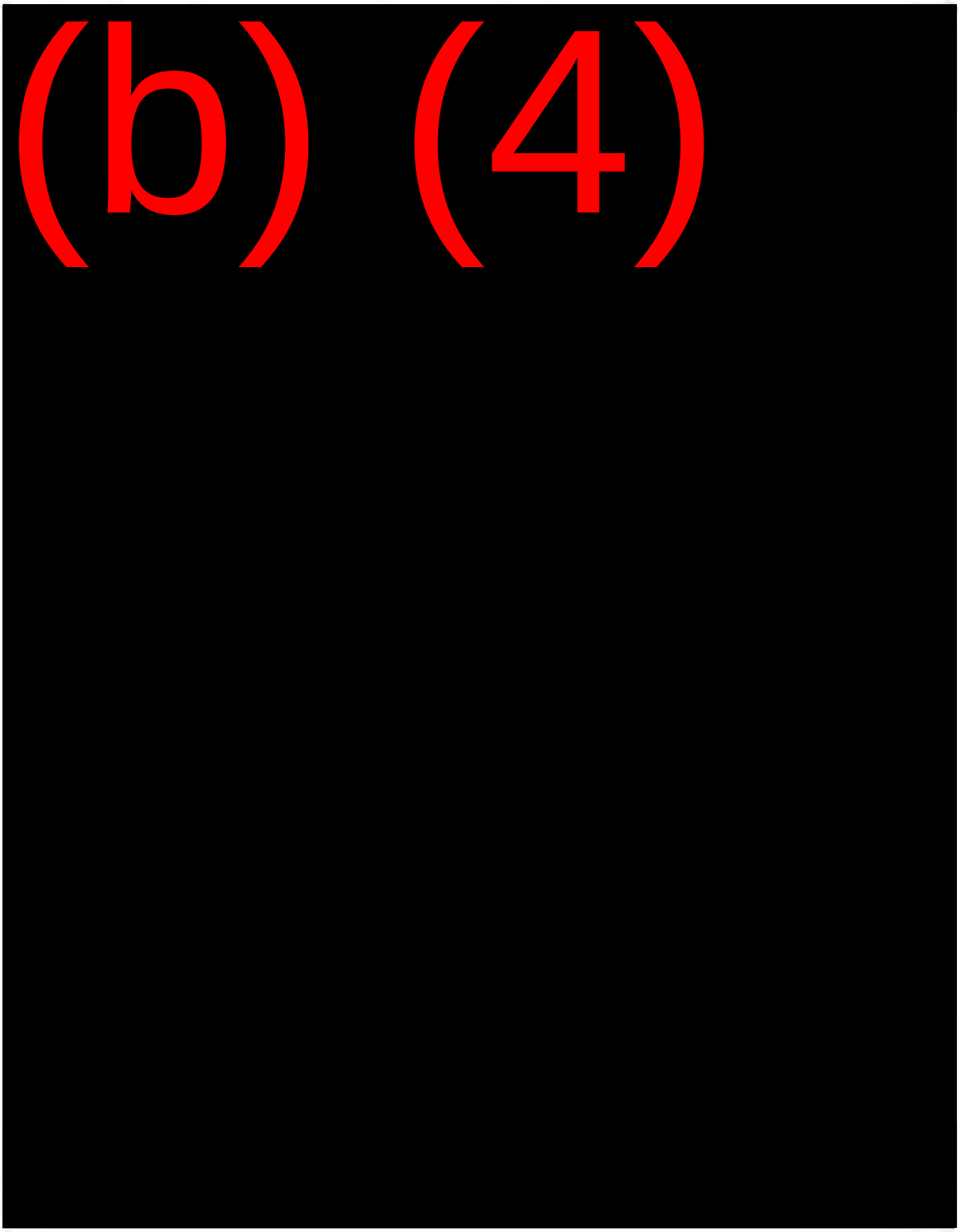
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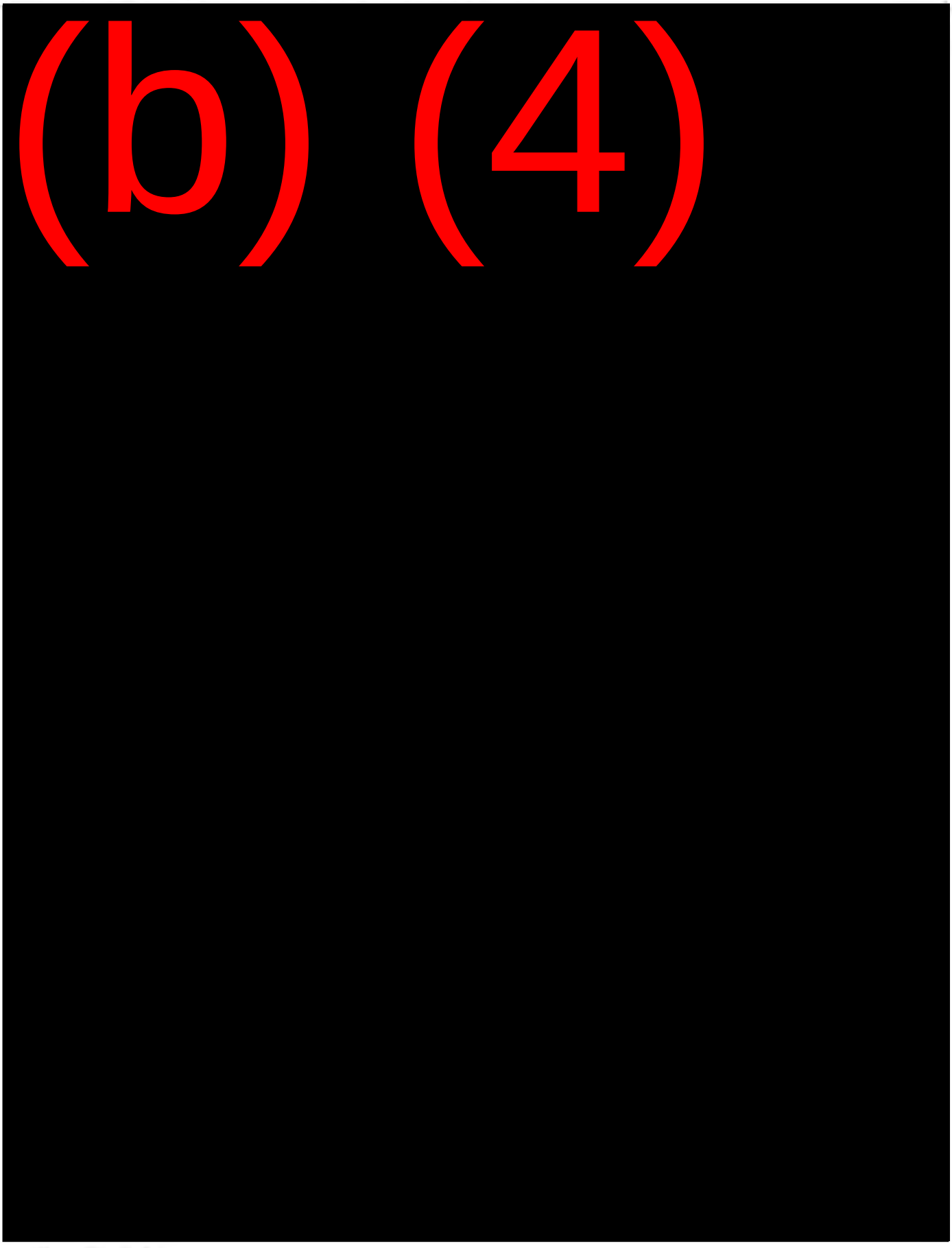
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ARTICLE F.2. DELIVERABLES SCHEDULE

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 "Summary of Contract Deliverables" in accordance with the stated delivery schedule.

The items specified below under heading 1 "Summary of Contract Deliverables", as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. **Summary of Contract Deliverables**

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the contracting officer representative (COR), contract specialist (CS), and contracting officer (CO) as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine-readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	**Meetings**		
01.6	Daily check in with project staff for **COVID-19 Contract**	Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case	• No agenda will be required for the meeting • No meeting minutes are required • Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	
02	**Technical Reporting**		
02.8	Product Development Source Material and Manufacturing Reports and Projections	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites. **The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates", on any contract/agreement that is manufacturing product for the USG**	• Contractor will submit Product Development Source Material Report ○ Within month of contract award ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or on the 6th month contract anniversary. • Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed	Contractor will submit Work Locations Report:

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	• Within 5 business days of contract award • Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
09	**Advanced R&D Products**		

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
09.5	Contractor Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during the COVID-19 Pandemic. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this contract and consistent with Good Publications Practices. Sponsor must publish the primary endpoint analysis. Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this contract and consistent with Good Publication Practices sponsor shall publish clinical trial data. If the contractor does not elect to publish data, Contractor shall provide CO and COR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the contractor involvement.	• Contractor shall notify CO and within 30 of primary analysis results and study end date [last subject last visit] if they plan not to publish data. • Within 10 calendar days of a request for clinical data from the CO, the Contractor shall provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical trial data funded in part or whole under this contract
09.6	Additional Clinical Trial Deliverables	Contractor shall provide read-only access to clinical trials management system (b) (4) [redacted] Contractor shall provide for review for all study operational	Contractor shall provide upon request of the CO or COR.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		plans prior to finalization including but not limited: 1. Global communication plan 2. Project management plan 3. Study subject recruitment/retention plan 4. Clinical monitoring plan 5. Medical monitoring plan 6. Safety management plan 7. Laboratory manual 8. Study procedures manual 9. Sample management plan 10. Clinical supply management plan 11. Quality management plan 12. Data management plan 13. Statistical analysis plan	

C.4 Target Product Profile

(b) (4)

H.19 Security

BARDA Security Requirements:
All COVID-19 contracts are required to address security requirements. In the event that Moderna does not have another contract in place with the USG within 45 days of execution of this contract modification that incorporates the security requirement, Moderna will submit a cost estimate for implementing security requirements for this contract. Moderna will be entitled to an equitable upward adjustment in the value of this contract to cover all additional costs associated with additional security requirements imposed by the Government.

H.20 Organizational Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non- public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall:

(1) enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a cmporate basis shall be furnished to the CO within fifteen (15) calendar days of execution

H.21 Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance pf this contract, except authorized by Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H. 22 PUBLICATION AND PUBLICITY

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).
(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.